Claims

1. An isolated cell derived from luminal epithelial cells of a mammary gland which is capable of proliferating and differentiating into cells of mammary gland luminal epithelial and myoepithelial cell lineages said isolated cell being capable of forming a cell culture comprising cells which are positive staining for the luminal epithelial marker ESA (ESA+) and negative staining for sialomucin (MUC-), so-called (ESA+/MUC-) cells.

2. A cell according to claim 1, which is isolated from suprabasal luminal epithelial cells of the mammary gland.

3. A cell according to claim 2, which is a human cell.

4. A cell according to any of claims 1 - 3, which is immortalised.

5. A cell population composed of cells according to any of claims 1 - 4.

6. An immortalised cell line derived from the cell of claim 4.

7. An immortalised cell line according to claim 6, wherein the immortalising step comprises transfecting the cells with a nucleic acid molecule encoding an immortalising polypeptide.

8. An immortalised cell line according to claim 7, wherein the immortalising step comprises transfecting the cells with a nucleic acid molecule encoding a papillomavirus polypeptide selected from the group consisting of E6, E7 and a nucleic acid molecule comprising E6 and E7.

9. An immortalised cell line according to claim 7, wherein the immortalising step comprises transforming the cells with at least one retroviral vector including an expression cassette comprising a nucleic acid molecule encoding a papillomavirus polypeptide selected from the group consisting of E6, E7 and a nucleic acid molecule comprising E6 and E7, and selecting the immortalised cells.

10. An immortalised cell line according to claim 9, wherein the immortalising step is performed by transforming the cells with retrovirus-containing supernatant from the PA317 LXSN HPV16E6E7 cell line and selecting the immortalised cells.

11. An immortalised cell line according to any of claims 6 - 10 that in culture is capable of forming branching structures resembling terminal duct lobular units of the mammary gland in morphology and/or by marker expression.

12. An immortalised cell line according to any of claims 6 - 11 which comprises cells that are positive staining for the keratin K19.

13. An immortalised cell line according to any of claims 6 - 12 that is derived from a cell selected from the group consisting of a rodent cell, a porcine cell, a ruminant cell, a bovine cell, a caprine cell, a equine cell, a canine cell, a ovine cell, a feline cell and a primate cell.

14. An immortalised cell line according to claim 13 that is selected from the group consisting of cells from mice, rats and rabbits.

15. An immortalised cell line according to claims 13 that is a human cell line.

16. The immortalised cell line according to claim 6 which is deposited in accordance with the provisions of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure at Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH (DSMZ) and has obtained the accession number DSM ACC 2529.

17. A method for isolation of an at least bi-potent mammary gland tissue cell, comprising the steps of:

(i) separating said tissue into two or more different cell types

(ii) culturing each of said different cell types under cell differentiation conditions and

(iii) selecting the cell type(s) that is/are capable of differentiating into at least two morphologically and/or phenotypically different cell types.

18. A method according to claim 17 in which the at least bi-potent cell is a cell according to any of claim 1-4.

19. A method for testing the toxic effect, if any, of a substance on mammary gland epithelial cells, the method comprising:

(i) culturing or maintaining the cells of any of claims 1 - 16 in a non-toxic medium;

(ii) adding the substance to be tested to the medium; and

(iii) determining the response, if any, of the cells, including changes in cell growth rate, cell death rate, apoptosis, cell metabolism, inter- as well as intra-cellular communication, morphology, mRNA or protein expression and antigen expression.

20. A method for testing the carcinogenic effect, if any, of a substance on mammary gland epithelial cells, the method comprising:

(i) culturing the cells of any of claims 1 - 16 in a growth medium which maintains the cells as non-transformed cells;

(ii) adding the agent, compound or factor under test to the cell culture; and

(iii) determining the neoplastic response, if any, of the so contacted cells by changes in morphology, tumorigenicity in animals, mRNA expression and/or antigen expression as well as other changes which is associated with carcinogenicy.

21. A method as claimed in claim 20, wherein the tumorigenicity test comprise the introduction of said treated cells into an immune incompetent test animal.

22. A method of testing the ability, if any, of a substance to modulate the differentiation of non-terminal differentiated mammary gland epithelial cells, the method comprising:

(i) culturing or maintaining the cells of any of claims 1 - 16 in a medium which in tiself does not modulate the differentiation;

(ii) adding the substance under test to the cell culture; and

(iii) determining the differentiation modulation responses, if any, of the so contacted cells by changes in cell growth rate, cell death rate, apoptosis, cell metabolism, inter- as well as intra-cellular communication, morphology, mRNA or protein expression or antigen expression as well as other changes which is associated with differentiation.

23. A method for screening a substance for its ability, if any, to interact with a cellular protein, the method comprising:

(i) transfecting a cell of any of claims 1 - 16 with a gene construct enabling transfected cells to express said protein;

(ii) adding the substance to be tested to the cells; and

(iii) determining the interaction, if any, with a cellular protein by changes in cell growth rate, cell death rate, apoptosis, cell metabolism, inter- as well as intra-cellular communication, morphology, mRNA or protein expression, antigen expression or other changes which either directly or indirectly is supposed to be associated with said protein.

24. A method according to claim 23 in which said cellular protein is selected from the group consisting of estrogen receptor-alpha, estrogen receptor-beta and progesterone receptor.

25. A method of transplanting a vertebrate host with a cell according to any of claims 1-4, comprising the step of introducing the cell into the vertebrate host.

26. A method of *in vivo* administration of a protein or gene of interest to an individual in need thereof, comprising the step of transfecting the cell-population of any of claims 1 - 4 with a vector comprising DNA or RNA which expresses the protein or gene of interest and introducing the transfected cell into said individual.

27. Use a cell according to any of claims 1 - 4 to prevent and/or treat cellular debilitations, derangements and/or dysfunctions and/or other disease states in mammals, comprising administering to a mammal a therapeutically effective amount of said cells, or cells or tissues derived therefrom.

28. A method of tissue repair or transplantation in mammals, comprising administering to a mammal a therapeutically effective amount of a cell according to any of claim 1 - 4, or cells or tissues derived therefrom.

29. A pharmaceutical composition comprising: a therapeutically effective amount of a cell according to any of claims 1 - 4, or cells or tissues derived therefrom; and a pharmaceutically acceptable carrier.

30. The pharmaceutical composition of claim 29 further comprising a proliferation factor or lineage commitment factor.

31. A diagnostic agent comprising the cell of any of claims 1 - 4, or any part thereof .